

Image 2

04-16-04

1636

Attorney's Docket No.: 24601-416C
(17084-018003)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : De Jong *et al.*
Serial No. : 10/086,745
Filed : February 28, 2002
Cust. No. : 20985
Title : METHODS FOR DELIVERING NUCLEIC ACID MOLECULES INTO
CELLS AND ASSESSMENT THEREOF

Art Unit : 1636
Examiner : Lambertson, D.A.
Conf. No. : 8781

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Transmitted herewith are a Supplemental Information Disclosure Statement and a check for the requisite fee of \$180 for filing in connection with the above-captioned application.

- [X] The Commissioner is hereby authorized to charge any fee that may be due under 37 C.F.R. §§ 1.16-1.17 in connection with this paper or with this application during its entire pendency to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed.

Respectfully submitted,

Stephanie L. Seidman
Reg. No. 33,779

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I hereby certify that this paper and the attached papers are being deposited with the United States Postal Services as "Express Mail" Label No. EV399294513 US in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

4/14/04

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Since this Supplemental Information Disclosure Statement is filed after the receipt of a first Office Action on the merits for the above-captioned application, the filing fee of \$180.00 is enclosed. If no proper payment is enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 06-1050.

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56 to inform the Patent Office of information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§ 1.97-1.98.

The Examiner's attention is directed to the reference Oberle *et al.* (*Biochimica et Biophysica Acta* (2004) 1676:223-230), accompanying the Supplemental Information Disclosure Statement filed March 26, 2004, in connection with the above-captioned application. Oberle *et al.* describes methods for delivering artificial chromosome expression systems (ACEs) to cells. Specifically, Oberle *et al.* demonstrates that when cells are treated with ultrasound energy and the cationic lipid SAINT-2 or DOTAP

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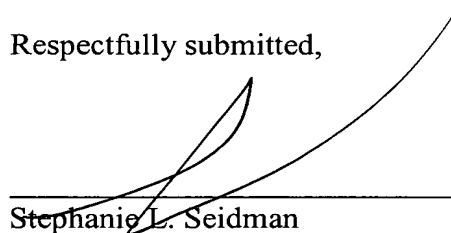
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prior to contacting cells with ACEs, the ACEs are delivered into the cells. Oberle *et al.* states that incubation of ACEs with cationic lipids such as SAINT-2 and DOTAP to prepare ACEs/lipid complexes leads to partial unravelling of the ACEs with a loss of their condensed structure (*see* page 225, col. 1, para. 2). Oberle *et al.* does not provide any data to support this statement.

The instant application describes complexation of ACEs with delivery agents such as cationic lipids to facilitate introduction of the ACEs into cells (*see, e.g.,* Examples 4-7). The instant application demonstrates that ACEs that are complexed with delivery agents such as cationic lipids can maintain their intact and condensed structure before and after delivery into the cells (*see, e.g.,* aforementioned Examples; *see also* de Jong *et al. Chromosome Res.* (2001) 9:475-485 and Vanderbyl *et al. Cytometry* (2001) 44:100-105, which are of record in this application).

Applicant respectfully requests that this reference be made of record in the file history of the above-captioned application.

Respectfully submitted,



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